SECTION 5 – 510(k) SUMMARY K061713

JUL 21 2006

[Submitted pursuant to 21 CFR 807.92(a). All data included in this document are accurate and complete to the best of DSC's knowledge.]

1. Submitter Information

Date:	June 8, 2006
Submitter:	Direx Systems Corporation 437 Turnpike Street Canton MA 02021
Telephone:	(339) 502-6013
Fax:	(339) 502-6018
Contact Person	Larisa Gershtein QA Manager
Contact Person e-mail address:	lgershtein@direxusa.com

2. Device

Trade/Proprietary Name:	MAGIS1, MAGIS2
Classification Name:	Accelerator, Linear, Medical
Regulation Number:	21 CFR 892.5050
Regulatory Class:	Class II (special controls)
Product code:	90 IYE
Panel:	Radiology Devices

3. Predicate Devices

Direx Systems Corp	MIGUE	(K052212)
BrainLAB AG	ExacTrac X-Ray 6D	(K040585)

4. Intended Use:

K061713

MAGIS1 / MAGIS2 intended use and indications for use are:

MAGIS1 / MAGIS2 is intended to aid in patient target to radiation beam set-up for administration of radiation therapy. It is indicated for all body procedures

Device Description

MAGIS1 and MAGIS2[1] are self-supported, added-on mobile imaging systems incorporating one or two X-ray channels respectively. MAGIS is mechanically coupled to the Linac Gantry and the couch, and is capable of rotating with both. MAGIS acquires and processes stereoscopic images for deriving localization data, in the form of discrepancy between planned and actual object position. Localization methods include markers triangulation and DRR comparisons to acquired images.

MAGIS incorporates X-ray production and detection modules mounted on extension arms attached to a Ring. The ring has a bore large enough to accommodate a patient and is operable to rotate about a horizontal axis, whereas said axis is parallel to couch direction and intersecting the isocenter.

MAGIS also incorporates a Console for user interface and for accommodation of the image acquisition, processing, display and user interface equipment.

5. Performance Testing

MAGIS was tested according to the following standards:

- IEC 60601-1 (1988) + A1(1991) + A2 (1995)
- IEC 60601-1-1 (2000)
- IEC 60601-1-2 (2001)+A1(2004)
- IEC 60601-1-3 (1994)

[1] Collectively referred to as MAGIS

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- IEC 60601-2-7 (1998)
- FDA CDRH 21CFR 1020.30
- FDA CDRH 21CFR 1020.32
- IEC 60601-1-4 (1996) + A1(1999)

6. Substantial Equivalence

MAGIS is a modification of its main predicate MIGUE (k052212). SE to BrainLAB's ExacTrac X-Ray 6D (K040585) is used for localization using DRR comparisons to acquired images.

MAGIS differences relative to its predicated devices do not raise additional safety or effectiveness issue as evidenced by performance validation.

Based on the descriptive information and the performance testing we believe that MAGIS is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 21 2006

Ms. Larisa Gershtein
Quality Assurance Manager
Direx Systems Corporation
437 Turnpike Street
CANTON MA 02021

Re: K061713
Trade/Device Name: MAGIS1 and MAGIS2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: June 8, 2006
Received: June 19, 2006

Dear Ms. Gershtein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DiREX
SYSTEMS CORP.

SECTION 4: INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known): K061713

Model Names:

MAGIS1; MAGIS2

Indications for Use:

MAGIS1; *MAGIS2* is intended to aid in patient target to radiation beam set-up for administration of radiation therapy. It is indicated for all body procedures

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓ OR Over the Counter Use_____
(Per 21 CFR § 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061713

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